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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,589	01/31/2002	Roger Q. Roberts	2860	3409

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WALTER A. HACKLER
2372 S.E. BRISTOL, SUITE B
NEWPORT BEACH, CA 92660-0755

EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,589

Applicant(s)

ROBERTS ET AL.

Examiner

Dwayne K. Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings were received on 6/23/2005. These drawings are approved.

Inventorship

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-3 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gubernator et al. (6,436,351) in view of Kedar et al. (6,083,761) and further in view of Day (6,558,631). Gubernator teaches a multiwell reaction system. The device is best described in column 3, lines 50 through column 4, line 35:

(2) As is seen in FIGS. 1A, 1B and 2, the present invention provides a multi-well microtitre reaction system 15 comprising a support rack 16, having an array of reaction wells 18. Optionally, system 15 may include **a reactor cap assembly 19 with an array of reactor caps 20 extending into wells 18**. A porous gas distribution plate 22, having an array of holes 23 passing therethrough, is captured between support rack 16 and a gasket 24. (Alternatively, if optional assembly 19 is included, gas distribution plate 22 is captured between assembly 19 and gasket 24). System 15 further comprises a top cover 26, used to retain all of the system components together, having a plurality of holes 27 passing therethrough. Retaining clips 28, which are preferably formed integral with top cover 26, extend downwardly to matingly interlock with notches 21 in the side of support rack 16, thereby holding the system together, as is seen in FIGS. 2, 3A and 3B. The present design provides a sealed reaction environment for each of the reaction wells 18 and eliminates the problems of spillage, leakage, evaporation loss, airborne contamination of well contents, and inter-well cross-contamination of liquid samples as will be explained.

(3) In a first preferred embodiment as seen in FIG. 3A, the array of reaction wells 18 is integrally formed together with support rack 16 as a single unit, preferably from a block of injection molded polypropylene.

(4) In a second preferred embodiment, as seen in FIG. 3B, the array of reaction wells 18 comprises selectively removable reaction tubes which are each separately received in an array of passages 17 formed in support rack 16. In this second embodiment, each separately removable reaction well 18 operates to seal a separate passage 17, such that a sealed reaction environment above the array of reaction wells 18 is provided. In this embodiment, reaction tubes comprising wells 18 are preferably formed from glass or polypropylene and support rack 16 is preferably formed from polypropylene.

(5) **Optional reactor caps 20 are preferably formed from polypropylene and operate to substantially eliminate spillage, leakage, evaporation loss and inter-well cross-contamination among wells 18, as follows. As can be seen in FIGS. 3A to 9, each reactor cap 20 has an upper sealing plug portion 34 and a lower funnel cone portion 36.**

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Sealing plug portion 34 is dimensioned to be slidably press fit into the open top end 30 of reaction well 18. Liquids received through a central vent 38 in each reaction cap 20 will pool at the closed bottom end 32 of each reaction well 18 as shown. Funnel cone portion 36 is dimensioned to extend inwardly into reaction well 18 and preferably terminates at a generally centrally located position in reaction well 18. Such generally funnel-shaped reactor caps, which are inserted into the top open end of a reaction well and terminate at a generally centrally located position in the reaction well, are known to exist.

The Examiner considers the reactor cap assembly (element 19) to be the element meeting the limitation of a matt having a plurality of wells having a size and shape such that it abuts the wells. The reactor cap assembly (19) has an array of reactor caps (20) with each reactor cap being comprised of an upper sealing plug portion (34) and a lower funnel cone portion (36). The upper sealing plug portion (34) abuts the top end (30) of well (18). Gubernator does not teach a pressure sensitive unidirectional valve in each of the wells. Kedar teaches a method of combining and transferring reagents in stacked plates. The embodiment of most relevance to the instant claims is shown in Figures 4, 5D, and 5E. As shown in Figure 4, the device is comprised of two elements, an upper element (12) having wells that are placed over and into the exits of the wells (22) of the lower element (14). Compounds are mixed and reacted in the wells of the upper plate and then transferred to the lower plate through centrifugation, vacuum or other forces (col. 10, lines 30-39). In Figures 5D and 5E, Kedar shows an embodiment with a tapered well having a "transitory hole" (34') that is flexible and normally closed. Upon centrifugation or application of vacuum, the hole flexes open and allows for the passage of fluid. When the force is removed, the hole closes again (col. 13, line 62 – col. 14, line 6). The Examiner considers this feature to be a unidirectional valve as required in the independent claim. It would have been

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obvious to one of ordinary skill in the art to add the valves from Kedar to the assembly of Gubernator. One would add the valves to the caps to control flow of liquid or gas through the end (37) of each cap. The combined teachings of Gubernator and Kedar teach every element of claims 1-3 and 20-22 except for a perforated mat. Gubernator teaches an interlocking web (39) made of a single piece of material that holds the array of reactor caps (20) together (See Figure 8 and column 6, lines 14-25), but does not teach a perforated web.

Day (6,558,631) teaches a multiwell plate comprised of a plurality of discrete tubes held in an array by a plate. The plate has one or more section lines that are adapted to facilitate dividing up the multiwell plate into subunits (Abstract). The section lines or slits (21-25) are shown in Figure 1A and described in columns 3 and 4. In column 4, lines 33-43, Day teaches the use of perforations instead of slits to form the division between subunits of the array. It would have been obvious to one of ordinary skill in the art to combine the perforation teaching from Day with the combined teachings of Gubernator and Kedar. One would add the perforations to the interlocking web (39) in order to separate individual units or subunits from the array as suggested by Day.

5. Claims 4-6 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gubernator et al. (6,436,351), Kedar et al. (6,083,761), and Day (6,558,631) and further in view of Harris (4,473,094). Gubernator, Kedar and Day, as combined above in paragraph 4, teach every element of claims 4-6 and 23-25 except for a duck billed

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valve in each of the matt wells. Harris teaches an air inlet that admits filtered gases into a fluid container that has a duck billed valve in the inlet housing. The presence of the duck billed valve prevents fluid from contacting the air filter to reduce the risk of bacterial contamination due to back flow through the valve (Abstract, col. 4, lines 1-23). It would have been obvious to one of ordinary skill in the art to combine the duck billed valve from Harris with the device of Kedar. One would add the duck billed valve from Harris to aid in the prevention of fluid flowing back through the valve while drawing fluid through the valve and into the lower plate.

Response to Arguments

6. Applicant's arguments, filed 6/23/2005, with respect to the rejection(s) of claim(s) 1-3 and 20-22 under Gubernator and Kedar have been fully considered and are persuasive. Applicant has amended claims 1 and 20 to include the limitation of a perforated matt. This feature is not taught in Gubernator or Kedar. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gubernator, Kedar and Day. Please see paragraph 4 above.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mathus et al. (6,890,488), Wijnschenk et al. (6,776,964), Boulton et al. (6,500,390) and Berray et al. (6,455,005) teach devices for closing an array of

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containers. Donofrio (3,021,001) shows an array of separable containers connected by material having perforations. Nugent (4,134,512) shows a stopper having a one way check valve.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
August 15, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700